Issued to:

Shandong IntcoMedical Products Co. Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
262506
China

Notified Body: 2777

SATRA customer number: P1720

EU Type-Examination Certificate

Certificate number: 2777/11804-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

697024575

Blue 697024575 601-605

Violet 697024575 631-635

White 697024575 641-645

Black 697024575 651-655

Description:

Five fingered disposable nitrile non-sterile gloves.

Sizes:

6/XS, 6.5/S, 7/M, 8/L, 9/XL

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	**Level**	**EN 374-4: 2013**
40% Sodium Hydroxide (K)	6	-11.5 %
30% Hydrogen peroxide (P)	2	-9.5%
37% Formaldehyde (T)	3	7.4 %
EN ISO 374-5: 2016		
Protection against Bacteria and fungi	Pass	
Protection against viruses	Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0278438/1848
SGS: QDHL1806013113OT, CH:TX:6420074520, CH:TX: 9420020333, CH:TX: 9420029243 CH:TX: 9420026599-1, CH:TX: 9420014953-1, CH:TX: 9420026316-1, CH:TX: 9420614959
TUV: 721642857-2

Signed on behalf of SATRA: Tara Saunders Geoff Graham

Date first issued: 30/01/2019
Date of issue: 30/01/2019

Expiry date: 30/01/2024

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

EU Declaration of Conformity

1. PPE：Disposable Vinyl Gloves

   Glove sizes available: XS, S, M, L, XL (6, 7, 8, 9,10)

2. Manufacturer　　Name:　Anhui Intco Medical Products Co., Ltd.

   Address: No.1 Haitang Road,Suixi District economic development area,Huaibei City,Anhui Province.

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Anhui Intco Medical Products Co., Ltd.

4. Object of the declaration: Disposable Vinyl Gloves （Clear-VGPF; Yellow-SMPF; Blue-BMPF; White-WMPF）

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: EN420:2003+A1:2009, EN ISO 374-1:2016 +A1:2018, EN374-4:2014, EN ISO 374-5:2016;

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

7. The notified body SATRA Technology Europe Ltd (Number: 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate.

8. The PPE is subject to the conformity assessment procedure Module C2 under surveillance of the notified body : SATRA Technology　(Number: 2777),

Adress: Bracetown Business Park Clonee, D15 YN2P, Ireland.

Signed for and on behalf of:　Anhui Intco Medical Products Co., Ltd.

签名 Signature　崔忠强

职位 Position　Quality Manager

日期 Date　5-May-2020

Test Report

Client name
Client address

Sample Description	:	SYNTHETIC VINYL EXAM GLOVES
Lot No.	:	NOT PROVIDED
Lot Size	:	NOT PROVIDED
Sample Quantity	:	280PCS

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

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Sample Receiving Date	:	APR.14,2020
Test Performing Date	:	APR.14,2020 TO APR.29,2020
Test Performed	:	SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	:	ASTM D 5250-19 STANDARD SPECIFICATION FOR POLY (VINYL CHLORIDE) GLOVES FOR MEDICAL APPLICATION (CLAUSE 6.1.2, 6.1.3, 6.1.4, 6.1.5)
Test Result(s)	:	PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	:	THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

scan to see the report

QDHL2004002960MD

Jessica Gao
Approved Signatory

Test Conducted:

ASTM D 5250-19 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application

Number of test sample	:	231 Piece(s)

Clause	Test Items	Result	Note
6.1.2	Freedom from holes	Pass	#1
6.1.3	Physical dimensions	Pass	#2
6.1.4	Physical property characteristics	Pass	#3
6.1.5	Powder residue for powder free gloves	Pass	#4

Notes : #1 See result 1
#2 See result 2
#3 See result 3
#4 The average mass of powder per glove is 0.04mg (Requirement: ≤ 2.0mg)

Test Result:

Result 1: Freedom from Holes

Sample Quantity: 200 Ac: 10 Re: 11 Found: 0

Result 2: Physical dimensions

Sample Quantity: 13 Ac: 1 Re: 2 Found: 0

Sample No.	Size: M			
			Median value/mm	
	Length/mm	Width/mm	Thickness-finger	Thickness-palm
1	238	96	0.082	0.091
2	237	98	0.094	0.098
3	237	98	0.092	0.092
4	240	96	0.093	0.097
5	232	97	0.092	0.096
6	236	98	0.092	0.097
7	230	96	0.094	0.093
8	234	96	0.083	0.095
9	235	97	0.081	0.094
10	239	98	0.113	0.093
11	240	97	0.092	0.095
12	242	98	0.135	0.091
13	239	98	0.143	0.095
Standard requirement	≥230	95±5	≥0.08	≥0.08
Found	0	0	0	0

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Result 3: Physical property characteristics

Sample Quantity: 13 Ac: 1 Re: 2 Found: 0

Force at break before aging

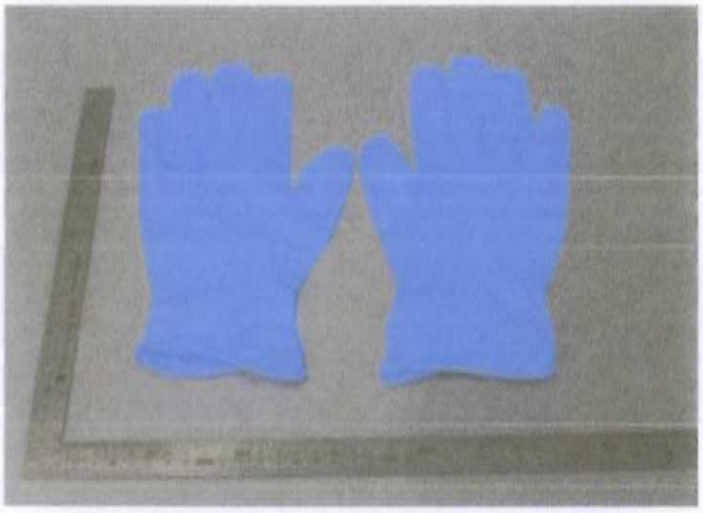
Sample No.	Size: M	
	Tensile strength (Mpa)	Ultimate Elongation (%)
1	16	313
2	16	394
3	17	344
4	19	364
5	18	365
6	20	395
7	19	372
8	17	346
9	21	404
10	18	349
11	18	365
12	19	366
13	19	368
Standard requirement	≥11	≥300
Found	0	0

Force at break after aging

Sample No.	Size: M	
	Tensile strength (Mpa)	Ultimate Elongation (%)
1	19	370
2	20	409
3	18	382
4	19	374
5	20	378
6	18	356
7	16	347
8	19	360
9	18	372
10	16	307
11	18	368
12	17	340
13	18	357
Standard requirement	≥11	≥300
Found	0	0

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:



SGS authenticate the photo on original report only

End of Report

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